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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/505,416 | 06/13/2005 | Hiroshi Kawazoe | 042717 | 7425 |

38834 7590 11/26/2008
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| EXAMINER |
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HURST, JONATHAN M

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

4153

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| MAIL DATE | DELIVERY MODE |
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11/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,416

Applicant(s)

KAWAZOE ET AL.

Examiner

JONATHAN M. HURST

Art Unit

4153

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/DE)
Paper No(s)/Mail Date 8/24/04, 6/20/06, 12/29/06, 3/27/07, 7/3/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7, 10-11, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US 2002/0015952).

Regarding claim 1 Anderson et al. discloses a support unit for a microfluidic system (See [003], Fig. 1, and Fig. 4), comprising: a first support; (See [0014] and Fig. 4 31 and Fig. 1 where underlying arrays are a support see [00235]) a first adhesive layer provided on a surface of the first support (See [0133] and [0189] where adhesive surface is used to attach arrays); and a hollow filament laid on a surface of the first adhesive layer to have an arbitrary shape and functioning as a flow channel layer of the microfluidic system. (See [0090], [0133], and [0063] where microarray chip contains a bundle of small plastic rods and alternatively Fig. 1 where first support is an underlying flat array 2 made of hollow filaments 1 see [0235])

Regarding claim 2 Anderson et al. discloses a support unit for a microfluidic system (See [003]), comprising: a first support (See [0014] and Fig. 4 31 and Fig. 1 where underlying arrays are a support see [00235]); a first adhesive layer provided on a surface of the first support (See [0133], and [0189]); and a first hollow filament group constituted by a plurality of hollow filaments laid on a surface of the first adhesive layer and respectively functioning as a plurality of flow channel layers of the microfluidic system. (See [0090], [0133], and [0063] where microarray chip contains a bundle of small plastic rods and alternatively Fig. 1 where first support is an underlying flat array 2 see [0235])

Regarding claim 3 Anderson et al. discloses all the claim limitations as set forth above as well as the support unit further comprising: a second adhesive layer provided on a surface of the first hollow filament group; and a second support provided on a surface of the second adhesive layer. (See Fig. 1 where multiple arrays 2 are stacked to give a bundle 3 using adhesive see [0189] and [0235] where second support is an overlying second array attached to first array with adhesive)

Regarding claim 7 Anderson et al. discloses all the claim limitations as set forth above as well as the support unit wherein at least one of the plurality of hollow filaments is partially provided with an optically transparent portion. (See [0191] and Fig. 6 where bundle 50 contains optically transparent filaments 51)

Regarding claim 10 Anderson et al. discloses a manufacturing method of a support unit for a microfluidic system (See [0002], Fig. 1, and Fig. 4), comprising: forming a first adhesive layer on a surface of a first support; and laying a hollow filament on a surface of the first adhesive layer. (See Fig. 4, [0090], [0133], and [0063] where microarray chip contains a bundle of small plastic rods held by adhesive surface on a first surface and alternatively Fig. 1 where first support is an underlying flat array 2 made of hollow filaments 1 see [0235])

Regarding claim 11 Anderson et al. discloses a manufacturing method of a support unit for a microfluidic system ([0002], Fig. 1, and Fig. 4), comprising: forming a first adhesive layer on a surface of a first support; and laying a first hollow filament group constituted by a plurality of hollow filaments, on a surface of the first adhesive layer. (See Fig. 4, [0090], [0133], and [0063] where microarray chip contains a bundle of small plastic rods held by adhesive surface on a first surface and alternatively Fig. 1 where first support may be an underlying flat array 2 made of hollow filaments 1 held together with adhesive see [0235] and [0189])

Regarding claim 14 Anderson et al. discloses all the claim limitations as set forth above as well as the manufacturing method of a support unit for a microfluidic system, after the laying the first hollow filament group, the manufacturing method further comprising: forming a second adhesive layer on a surface of the first hollow filament group; and adhering a second support onto a surface of the second adhesive layer.

(See Fig. 1 where multiple arrays 2 are stacked to give a bundle 3 using adhesive [0189] and [0235] where second support is an overlying second flat array attached to first array with adhesive)

3. Claims 2, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazier et al. (WO 00/16833)

Regarding claim 2 Frazier et al. discloses a support unit for a microfluidic system (See Fig. 1 and C 1 L 10-17) comprising: a first support (See Fig. 1 12) a first adhesive layer provided on a surface of the first support (See Fig. 1 and C 11 L 54-60 where microneedles 16 are bound to an interface using epoxy and C 7 L 45-50 where arrays of needles are placed on a substrate and bonded using adhesive); and a first hollow filament group constituted by a plurality of hollow filaments laid on a surface of the first adhesive layer and respectively functioning as a plurality of flow channel layers of the microfluidic system. (See Fig. 1 16 and Abstract)

Regarding claim 5 Frazier et al. discloses all the claim limitations as set forth above as well as the support unit wherein the plurality of hollow filaments is partially exposed from the first support. (See Fig. 1 where end of needles 18 are exposed from support 12 and C 3 L 55-67)

Regarding claim 6 Frazier et al. discloses all the claim limitations as set forth above as well as the support unit wherein a metal film is formed on a part of at least one of the plurality of hollow filaments. (See Fig. 1 C 7 L 8-14 where microneedles 16 are coated with gold and C 4 L 43-54 where microneedles can be formed from metal materials)

Claim Rejections - 35 USC § 102 or 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 4, 11, and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Durst et al. (DE4308697)

Regarding claim 2 Durst et al. discloses a support unit for a microfluidic system (See Fig. 1 and Abstract) comprising: a first support (See Fig. 1 4); and a first hollow filament group constituted by a plurality of hollow filaments laid on a surface of the first support and respectively functioning as a plurality of flow channel layers of the microfluidic system. (See Fig. 1 where hollow filament group 1' is placed on top of support 4 and Abstract)

Durst et al., in Fig. 1 teaches a support unit for a fluidic system that appears to be the same as, or an obvious variant of the support unit comprising a first adhesive layer provided on the surface of a first support and hollow filament group laid on said first adhesive layer as set forth in the instant claim as the hollow filaments disclosed by Durst et al. are held in place to a support.

Regarding claim 4 Durst et al. discloses all the claim limitations as set forth above as well as the support unit further comprising a second hollow filament group constituted by a plurality of hollow filaments laid in a direction so as to intersect with the first hollow filament group (See Fig. 1 1 and 1' where a second hollow filament group 1 is placed on top of a first hollow filament group 1' in an intersecting direction) and functioning as another plurality of flow channel layers of the microfluidic system (See Abstract)

Regarding claim 11 Durst et al. discloses a manufacturing method of a support unit for a microfluidic system (See Abstract), comprising: forming a first support; and laying a first hollow filament group constituted by a plurality of hollow filaments, on a surface of the first support. (See Fig. 1 where hollow filament group 1' is placed on top of support 4)

Durst et al., in Fig. 1 teaches a support unit for a fluidic system that appears to be the same as, or an obvious variant of the support unit comprising a first adhesive layer provided on the surface of a first support and hollow filament group laid on said first adhesive layer as set forth in the instant claim as the hollow filaments disclosed by Durst et al. are held in place to a support.

Regarding Claim 13 Durst et al. discloses all the claim limitations as set forth above as well as the manufacturing method of a support unit for a microfluidic system, further comprising laying a second hollow filament group constituted by a plurality of hollow filaments in a direction so as to intersect with the first hollow filament group, after the laying the first hollow filament group. (See Fig. 1 1 and 1' where a second hollow filament group 1 is placed on top of a first hollow filament group 1' in an intersecting direction)

Claim Rejections - 35 USC § 103

7. Claims 8-9, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson as applied to claims 1-3, 7, 10-11, and 14 above, and further in view of Wolk (US 6,148,508).

Regarding claims 8-9 Anderson et al. discloses a support unit for a microfluidic system (See [003], Fig. 1, and Fig. 4), comprising: a first support (See [0014] and Fig. 4 31 or alternatively Fig. 1 where support is an underlying array see [0235]); a first adhesive layer provided on a surface of the first support (See [0133] where adhesive surface is used to attach arrays to a first surface and [0189] where adhesive binds arrays); a plurality of hollow filaments laid on a surface of the first adhesive layer (See Fig. 4 where hollow filaments are on support 31 and Fig. 1 where arrays are bundled using adhesive see[0189]); a second adhesive layer provided on the first adhesive layer and the hollow filaments; a second support provided on a surface of the second adhesive layer; (See Fig. 1 where multiple arrays 2 are stacked to give a bundle 3 using adhesive see [0189] and [0235] where second support is a second overlying array attached to first array with adhesive)

Anderson et al. does not disclose a relay portion provided in the first adhesive layer and the second adhesive layer and connecting routes of the hollow filaments as well as the support unit wherein the relay portion includes a part of the second support.

Wolk discloses a support unit for a microfluidic system, comprising: a first support (See Fig. 4 B 402a) ; a plurality of channels laid on a surface (See Fig. 4A); a second support provided on a surface of the first support (See Fig. 4B 402b); and a relay portion provided in the first support and the second support and connecting routes of channels (See Fig. 4B where relay is formed by 42a and 442b and connects routes of channels 438 and 404) as well as the support unit wherein the relay portion includes a part of the second support. (See Fig. 4B substrate 402b and relay portion 442b). While Wolk does not specifically disclose the relay portion being formed in adhesive layers when substrates are bound using an adhesive, which is known in the art (See Wolk C 6 L 62- C 7 L 2), and relay portion such as 442 is formed in said substrates it must be formed through adhesive layers.

Wolk and Anderson et al. are analogous because both references teach the use of flow channels disposed between two substrates.

It would have been obvious to one of ordinary skill in the art at the time of invention to form a relay channel as described by Wolk in the support unit of Anderson because the relay channel provides an effective way of connecting channels and electrokinetically transporting material into a microarray as described by Anderson. (See Wolk C 1 L 45-63 and Anderson [0152])

Regarding Claim 15-16 Anderson et al. discloses a manufacturing method of a support unit for a microfluidic system (See [0002], Fig. 1, and Fig. 4) , comprising: forming a first adhesive layer on a surface of a first support (See Fig. 1 where support is an underlying array bound with adhesive see [0235] and [0189]); laying a plurality of hollow filaments on a surface of the first adhesive layer (See Fig. 1, [0090], [0133], [0189], and [0063] where filaments are attached to an adhesive surface); forming a second adhesive layer on the first adhesive layer and the hollow filaments (See [0189] and [0235] where second array is placed on top of a first array using adhesive); and adhering a second support onto a surface of the second adhesive layer. (See Fig. 1 where multiple arrays 2 are stacked to give a bundle 3 using adhesive see [0189] and [0235] where second support is a second overlying array attached to first array with adhesive)

Anderson does not disclose forming a relay portion in the first adhesive layer and the second adhesive layer wherein the forming of the relay portion in the first adhesive layer and the second adhesive layer further includes forming the relay portion so that the second support becomes a part of the relay portion.

Wolk discloses a manufacturing method of a support unit for a microfluidic system (See Abstract), comprising: forming a relay portion in a first adhesive layer and a second adhesive layer (See Wolk C 6 L20-36 While Wolk does not specifically disclose the relay portion being formed in adhesive layers when substrates are bound

using an adhesive, which is known in the art See Wolk C 6 L 62- C 7 L 2, and relay portion such as 442 is formed in said substrates it must be formed through adhesive layers); and adhering a second support onto a surface of the second adhesive layer (See Wolk C 6 L20-36 and Fig. 4B where second support 402b is adhered to first support 402a and capillary 404) wherein the forming of the relay portion in the first adhesive layer and the second adhesive layer further includes forming the relay portion so that the second support becomes a part of the relay portion. (See Fig. 4B substrate 402b and relay portion 442b and C 6 L20-36)

Wolk and Anderson et al. are analogous because both references teach the use of flow channels disposed between two substrates.

It would have been obvious to one of ordinary skill in the art at the time of invention to form a relay portion in a first adhesive layer and a second adhesive layer of a microfluidic support unit as described by Wolk in the manufacturing method of a support unit for a microfluidic system described by Anderson because the relay portion provides an effective way of connecting channels and electrokinetically transporting material into a microarray as described by Anderson. (See Wolk C 1 L 45-63 and Anderson [0152])

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US2002/0015952) as applied to claims 1-3, 7, 10-11, and 14 above, and further in view of Matson et al. (US 5,429,807)

Regarding claim 12 Anderson et al. discloses all the claim limitations as set forth above but does not disclose a manufacturing method of a support unit wherein, between the forming the first adhesive layer and laying the first hollow filament group, the manufacturing method further comprising: providing release layers on the surface of the first adhesive layer at positions where the hollow filaments are exposed; and providing a slit in the first support, wherein the first hollow filament group is laid to be in contact with both surfaces of a pair of the release layers.

Matson et al. discloses a manufacturing method of a support unit (See Abstract) comprising providing release layers at positions where channels are exposed (See Fig. 2 channels 14 are exposed through release layers 18 and 19); and providing a slit in a first support (See Fig 2 18 and 19 and C 3 L 50-59 where holes are slits formed in a support plate), wherein the channel group is laid to be in contact with both surfaces of a pair of the release layers. (See Fig. 2 where channels 14 are in contact with surfaces of release layers 18 and 19)

Matson et al. and Anderson et al. are analogous because both references disclose a device containing multiple flow channels on a substrate and a method of manufacturing said device.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the release layers of Matson et al. to the support unit of Anderson et al. because the release layers allow the feeding and release of chemicals to a plurality of channels (See Matson C 3 L 50-59) as required by Anderson et al. (See Anderson [0223])

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./
Examiner, Art Unit 4153

/Basia Ridley/
Supervisory Patent Examiner, Art Unit 4153